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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,607	11/04/1998	WOLF-GEORG FORSSMANN	P63132USO	8253

7590

05/11/2004

JACOBSON PRICE HOLMAN & STERN  
400 SEVENTH STREET NW  
WASHINGTON, DC 20004

EXAMINER
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HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/171,607	<b>Applicant(s)</b> FORSSMANN ET AL.	
	<b>Examiner</b> Maher M. Haddad	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 78-91 is/are pending in the application.  
     4a) Of the above claim(s) 91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 78-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 2/12/04, is acknowledged.
2. Claims 78-91 are pending.
3. Claim 91 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
4. Claims 78-90 are under consideration in the instant application.
6. The following new ground of rejection is necessitated by the amendment submitted 2/12/03.
7. Claim 81 is objected to for the following informalities: claim 81 recites "In a process", it is improper to recite "in a process", the claim should recite "A process"
8. The following is a quotation of the second paragraph of 35 U.S.C. 112.  
*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*
9. Claims 81 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.  
  
A. The "process for the preparation of a peptide comprising expressing the peptide" recited in claim 81, line 1 is indefinite and ambiguous. Such process require a DNA encoding the peptide of SEQ ID NO:1.
10. In view of the amendment filed on 2/12/04, only the following rejection is remained.
11. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*
12. Claims 78-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention for the same reasons set forth in the previous Office Action mailed 8/12/03.

Applicant's arguments, filed 2/12/03, have been fully considered, but have not been found convincing.

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Regarding the usefulness of the invention as medicament, Applicant directs the Examiner's attention to the PTO Guidelines under the Utility section. Applicant contends that the PTO Office fails to set forth "any evidence of record" sufficiently credible to support the allegations of failure to enable. Further, Applicant submits that the rejection has failed to establish a prima facie case for lack of enablement for "using" the invention. Applicant contends that no "support" is provided in the outstanding Office Action for the rejection. Applicant further submits that nothing by way of scientific reasoning or evidence is provided in the outstanding Office action to rebut the applicant's assertion of usefulness. Applicant further states that lack of enablement is not established by mere allegations of undue breadth, i.e. that claims read on non-disclosed embodiments.

Applicant's assertion that Applicant is not required to provide in vivo data to establish that the skilled artisan is enabled to make and use the claimed invention appears to confuse the issue of utility with enablement. The usefulness (utility) of the invention is not at issue. Rather, the specification is held not to enable the use of the claimed invention. In the instant case, while Applicant's provision of in vitro data does appear to be sufficient to establish that peptide of SEQ ID NO:1 functions as a medicament commensurate in scope with the instant claims, nor does the skilled artisan recognized the instant medicaments commensurate in scope with the instant claims, nor does the skilled artisan recognize a reasonable correlation between the in vitro data provided and the in vivo use recited.

Applicant further argues that the literature recognizes a role for another fragment of collagen, "endostatin" is useful for treating angiogenesis dependent diseases such as cancer and draws the Examiner attention to the following references:

"MULTIPLE ALIGNMENT" between claimed full length(hCol-18), endostatin (Hfcol-Pat) and mouse. Further Applicant draws the Examiner's attention to the website of EntreMed Inc. to demonstrate evidence that endostatin was the subject of clinical trials in which angiogenesis inhibition was shown to have occurred.

Regarding U.S patent No. 6,174,861, the "multiple alignment" and endostatin clinical trial, the Examiner notices that (a) claimed SEQ ID NO:1 is 87% homology to the C-terminal of hCol-18, (b) endostatin is refers to the N-terminal portion of the hCol-18, (c) the '861 patent provides in vivo efficacy to endostatin, finally, (d) Appendixes (A-C) do not address the issue at hand which is claimed SEQ ID NO:1. Therefore, undue experimentation would be required of the skilled artisan to determine the effect of SEQ ID NO: 1 on angiogenesis in vivo in view of the instant disclosure.

13. No claim is allowed.

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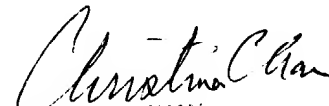
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.  
Patent Examiner  
May 10, 2004

  
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